Regulatory Agency Relations

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: [Docket No. 02D-0049] *Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product-Specific Advisory Committees*

Merck & Co., Inc, is a leading worldwide, human health product company that has produced many of the most important pharmaceutical products on the market, today. Merck's multidisciplinary Research and Development (R & D) is a highly risk-intensive process that depends upon a predictable regulatory environment. Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment.

In the course of bringing our product candidates through developmental testing, clinical trials, and, ultimately, to the marketplace, Merck frequently participates in FDA public advisory committee meetings and is very familiar with the advisory committee process and conflict of interest rules. Therefore, we are well qualified to comment on the subject of this *Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product-Specific Advisory Committees*, hereafter referred to as *The Draft Guidance*.

Comment 1: Reporting Requirements for SGEs and Clinical Investigators should be the same

Parameters outlined in *The Draft Guidance* pertaining to reporting requirements about compensation and financial interests of Special Government Employees (SGEs) serving on public advisory committees should be the same as requirements for collection of the same information from clinical investigators conducting clinical studies.[1] Often, SGE's who serve on advisory committees are selected from among experts in a medical specialty who have conducted clinical trials in that field. Their bias with regard to the outcome of a clinical study or a decision on an advisory committee considering that study could be judged to be similar and, therefore, their financial reporting obligations should be the same.

FDA determined that financial conflicts of interest of clinical investigators have the potential to directly influence the outcome of clinical trials and issued detailed guidance to address areas of concern. While SGE's on advisory committees may influence the timing of marketability of a product, their influence on the clinical data presented to them is not the same as that of clinical investigators, except as noted above. It is illogical for SGEs on advisory committees to be held to more stringent financial disclosure standards than those for clinical investigators.

[1] The requirements for clinical investigators are noted in applicable regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860) and the related *Guidance for Industry Financial Disclosure by Clinical Investigators*, dated March 20, 2001.

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Table 1 highlights areas where this *Draft Guidance* is inexplicably more stringent for SGEs serving on advisory committees, than the *Guidance for Industry Financial Disclosure by Clinical Investigators*.

The Draft Guidance	***Guidance for Industry Financial Disclosure by Clinical Investigators***
SGE's serving on advisory committees must report:	**Investigators must report:**
interest in a publicly held company *of any magnitude*	interest in a publicly held company in excess of $50,000 threshold
consulting fees *of any magnitude*	$25,000 threshold for "significant payments of other sorts" ("SPOOS"), including consulting fees and grants
contracts and grants *of any magnitude*	Contracts and grants included within SPOOS, with discretion

FDA reports significant expenditure of resources to implement and simplify reporting requirements for clinical investigators and this experience should not be ignored. Given this experience, it is counterintuitive for FDA to suggest in *The Draft Guidance* that ratcheting up the requirements for individuals serving on advisory committees is necessary or can be done without a negative impact on recruitment to these important committees. Further, if FDA collects more complicated but unnecessary financial data, it will be more difficult to justify waivers of financial conflicts of interest to allow unrestricted participation of advisory committee members.

Comment 2: Provide Definition for "Product-Specific Meetings"

It is not clear whether or not "product-specific meetings" includes advisory committee meetings during which there is discussion of guidances for a therapeutic class of drugs or advice for products treating specific diseases.

Summary of Recommendations:

A. To ensure that recruitment to advisory committees would not be jeopardized because of unusual or unnecessarily burdensome reporting requirements for financial conflicts of interest, *The Draft Guidance* should be consistent and compatible with *The Guidance for Clinical Investigators* in the nature and magnitude of the information required to be disclosed. Alternatively, justification for more stringent requirements needs to be presented publicly.

B. *The Draft Guidance* should clarify the definition of "product-specific meeting."

We welcome the opportunity to comment on this *Draft Guidance*.

Sincerely,

Marie Gray for

Bonnie J. Goldmann, MD
Senior Vice President
Global Strategic Regulatory Development

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